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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,021	08/27/2001	Roger G. Little II	11004US08 / 100-224.P1.C4	9954

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,021	LITTLE, ROGER G.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-14,16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) *1,3,6-13 and 18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 14, 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment filed 09/22/2003 has been entered. Claims 1, 3, 5-14, 16, 18-21 are pending. Applicant elected group III, claims 5, 14, 17, 22, in Paper No. 5. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction between group II, claims 2, 4, 14, 15, 16, and group III was withdrawn upon further consideration. Claims 1, 3, 6-13, 18-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5. Claims 5, 14, 16 are being examined.

Maintained Formal Matters, Objections, and/or Rejections:

Double Patenting

Claims 5, 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent Nos. 5627153, 5646114, 6013629, 6214789.

Applicant argues that the claims have been amended to render them patentably distinct from the claims of the patents. Applicant's arguments have been fully considered but they are not persuasive. The present claims have been amended to recite "contacting endothelial cells with." However, claims 4, 4, 8, and 14 of U.S. Patent Nos. 5627153, 5646114, 6013629, and 6214789, respectively, recite administering a BPI protein product intravenously. Insofar as endothelial cells line the entire vascular system (see Alberts

(U), page 1150, last full paragraph), then intravenous administration of a BPI protein product is contacting endothelial cells with a BPI protein product.

Claim Rejections - 35 USC § 102

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Opal (v6). The examiner also relies upon Alberts (U). Opal discloses the intravenous administration of BPI and protection from lethality following endotoxin challenge thereby (page 351A, right column, second Abstract). Applicant argues that Opal does not teach or suggest inhibiting endothelial cell proliferation by contacting endothelial cells with a BPI protein product. Applicant's arguments have been fully considered but they are not persuasive. Insofar as endothelial cells line the entire vascular system (see Alberts (U), page 1150, last full paragraph), then intravenous administration of a BPI protein product is contacting endothelial cells with a BPI protein product. No difference is seen between the amount administered to inhibit endothelial cell proliferation and the amount showing protection from lethality following endotoxin challenge.

Claim Rejections - 35 USC § 103

Claims 5, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Opal (v6) and Ooi (w6). The examiner also relies upon Alberts (U).

Opal discloses the intravenous administration of BPI and protection from lethality following endotoxin challenge thereby (page 351A, right column, second Abstract). Opal does not teach the administration of a 25-kDa fragment of BPI.

Ooi teaches a 25-kDa fragment of BPI that possesses the bactericidal and envelope-altering activities of the 60-kDa parent protein. On a molar basis, the fragment is as potent as holo-human BPI against rough Escherichia coli, is more potent than holo-BPI against more resistant smooth E. coli, and retains the specificity of BPI toward Gram-negative bacteria. NH_2-terminal amino acid sequence analysis shows that the fragment is derived from the NH_2 terminus of the BPI molecule. These findings suggest that all of the molecular determinants of the antibacterial properties of BPI reside within the NH_2-terminal 25-kDa segment, implying a novel structural/functional organization for a cytotoxic protein. See the Abstract. Ooi does not teach the administration of BPI and protection from lethality following endotoxin challenge thereby.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to intravenously administer BPI and protect from lethality following endotoxin challenge thereby, as taught by Opal, and to modify that teaching by intravenously administering the NH_2-terminal 25-kDa segment of BPI, as taught by Ooi, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because on a molar basis, the fragment is as potent as holo-human BPI against rough Escherichia coli, is more potent than holo-BPI against more resistant smooth E. coli, and retains the specificity of BPI toward Gram-negative bacteria, and all of the molecular determinants of the antibacterial properties of BPI reside within the NH_2-terminal 25-kDa segment. The intended uses of the claimed methods do not distinguish the claims from Opal and Ooi. No difference is seen between the amount administered to inhibit endothelial cell proliferation and the amount showing protection from lethality following endotoxin challenge. Insofar as endothelial cells line

the entire vascular system (see Alberts (U), page 1150, last full paragraph), then intravenous administration of a BPI protein product is contacting endothelial cells with a BPI protein product. The invention is prima facie obvious over the prior art.

Applicant argues that Opal and Ooi do not teach or suggest inhibiting endothelial cell proliferation by contacting endothelial cells with a BPI protein product. Applicant's arguments have been fully considered but they are not persuasive. Insofar as endothelial cells line the entire vascular system (see Alberts (U), page 1150, last full paragraph), then intravenous administration of a BPI protein product is contacting endothelial cells with a BPI protein product. No difference is seen between the amount administered to inhibit endothelial cell proliferation and the amount showing protection from lethality following endotoxin challenge.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 is indefinite since it depends from a canceled claim, and thus makes no sense, since it is incomplete. The metes and bounds are not clearly set forth.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
JANUARY 5, 2004